

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	William C. Brunnett et al.	Examiner:	David C. Comstock
Serial No.:	10/776,835	Group Art Unit:	3733
Filed:	February 11, 2004	Docket No.:	M190.147.101 / PD266.00
Title:	HIGH SPEED SURGICAL CUTTING INSTRUMENT		

DECLARATION OF WILLIAM C. BRUNETT SUBMITTED UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

I, William C. Brunnett, hereby declare that:

1. I currently reside at 11349 Tacito Creek Drive, Jacksonville, Florida 32223.
2. I received a bachelor of science degree in mechanical engineering from Ohio State University in 1986.
3. I have been employed as a mechanical engineer in various capacities since 1987. My employment history includes positions as a mechanical engineer with Brand Technologies from 1987-1993 and Micropolis Corp., from 1993-1998, designing and analyzing computer disk drive components, including failure analysis of high speed bearings. From 1998-2002, I was employed with Phillips Medical Systems as a mechanical engineer, designing and analyzing CT scanners, including fatigue analysis of multiple mechanical components. I have been employed with Medtronic Xomed, Inc., as a mechanical engineer since 2002, and am currently a Principal Mechanical Engineer. In this capacity, I design and analyze high speed surgical cutting instruments.
4. My educational background and employment efforts over the past twenty years have provided me with an intimate knowledge of mechanical component failure analysis as well as high speed surgical cutting instruments. I believe that I qualify as one of ordinary

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skill in the art of high speed surgical cutting instruments, and related systems and methods of use.

5. I am a joint inventor of the subject matter set forth and claimed in the above-entitled patent application. I have reviewed the Office Action mailed June 1, 2007 and an English translation of the French patent, FR 1,166,884, relied upon by the Examiner in rejecting the pending claims (hereinafter "FR '884").
6. FR '884 discloses a curved auricular trepan instrument comprised of a 0.8 mm piano wire rotatably disposed within a curved, metal sheath. As one of skill in the art, I do not believe that the teachings of FR '884 would suggest the high speed surgical cutting instrument inventions described and claimed in the pending application. In fact, I initially tested instrument constructions akin to the instrument described in FR '884 and found that the disclosed piano wire immediately failed when disposed within a curved metal tube and rotated at high speeds. For example, attached as Exhibit A are several pages from an inventor notebook I prepared on March 19, 2003, recording various surgical cutting instrument designs I prepared and tested. At page 12 of the inventor notebook, a "Test 1" is described in which an inner "music wire" (high carbon steel music wire, 0.020 inch diameter and akin to the piano wire described in FR '884) was rotated within a curved metal tube at 60,000 RPM. The inner wire failed after about 10 seconds. This same construction also failed even with the addition of a lubricant.
7. It is my belief that one of skill, upon viewing FR '884 in light of the test results set forth in Paragraph 6 above, would not consider or pursue a high speed surgical cutting instrument as described and claimed in the pending application. To the contrary, one of skill would search for an entirely different instrument construction. In fact, my knowledge of the surgical cutting tools available in the industry prior to our invention

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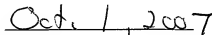
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reveals that no one considered that a wire rotated at high speeds within a metal tube could serve as the basis for a viable, high speed surgical cutting instrument.

8. In light of the above, as one of ordinary skill in the art, I do not believe that FR '884 or any other prior art provides a suggestion to utilize the teachings of FR '884 in constructing a high speed surgical cutting instrument as disclosed and claimed in the pending application, nor would one of ordinary skill in the art be motivated to so-modify the teachings of FR '884.
9. I declare that all statements made herein are of my own knowledge and are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful, false statements and the like so-made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of this application or any patent issuing thereon.

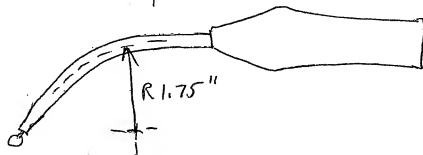

William C. Brunnett


Date

From Page No. _____

Proto type Configuration:

Part #		Description
11681782	Rev 1	Housing Curved Burr
11681783	Rev 1	Bur End, Spring Wire
11681784	Rev 1	Tubing, Curved Bur
11681785	Rev 1	Burr Wire, Curved Bur

Test 1:

- High Carbon Steel Music Wire, non stress relieved
.020" Dia, 350 KSI Min Tensile Strength
- no lubricant

Results:

- Music Wire fatigue failed after about 10 sec.
at 60 Krpm
- Tubing became too hot to touch at about 40k rpm
- Inside of tubing very rough
- The addition of white EP bearing grease made no difference on the fatigue failure limit and only a minimum improvement on tubing heat
- Failed wire had groove marks cut into the surface in the bend area.

Witnessed & Understood by me.

Date

Invented by

Date

Dore A. Oliver

2/19/2003

Recorded by

William C. Bennett

3-19-03

From Page No. ...

Test 2:

- Inside surface of tubing buffed out using string and lapping compound.
- Wire coated with White EP Bearing Grease

Results:

- fatigue failure limit same as in Test 1
- tubing became hot to the touch at about 60krpm

Test 3:

- Same as Test 2 except wire stress relieved at 375°F for 1 hr.

Result:

- fatigue failure at about 1.5 min. @ 60krpm

Test 4:

- Same as Test 2 except wire changed to Nitinol .020" Dia

Result:

- no fatigue failure after running for a total of 5 min. at 80K rpm
- runs fairly cool at 60K
- hot at 80K

Witnessed & Understood:

Date

Invented by

Date

Dana A. E. Oliver

3/20/2003

Reviewed by

William C. Bennett

3-20-03



French Republic

Ministry of Industry and Commerce
Industrial property service

Department of Industrial property

Invention Patent

Gr. 19. -C11 No 1.166.884
International classification A 61 b

[illegible seal]

Curved auricular trepan

A limited liability company named: ÉTABLISSEMENTS BEAUDOUIN residing in France (Seine).

Requested on the 19th of February 1957 at 1:01 p.m. in Paris

Issued June 30th 1958 --- Published November 17th 1958.

(Invention patent whose issue was postponed in execution of article 11, § 7 of the law of July 4th, 1844 modified by the law of April 7th, 1902.)

Surgical operations carried out in the inner ear through the auditory canal are particularly difficult due to its relatively large depth and narrow diameter such that the operator is working at the bottom of a cavity about 50 mm deep and several millimeters in diameter.

In particular, operations carried out on the boney or ossified parts of very small size for example the chain of ossicles require extremely delicate tools such as drills and reamers, on the order several of tenths of a millimeter and turning at high speed. Moreover, so that the permanent optical inspection of operations may be effective, the tools and notably the tool post must present on the one hand the smallest dimensions possible for the entire portion to be introduced into the ear and, on the other hand, a certain curvature so as to leave clear the axial region along which the luminous rays of a light source would be concentrated.

The invention in question due to the work of Mr. Moisy, concerns a surgical instrument meeting the preceding conditions. This tool is mainly made up of a stem made of a solid, flexible material, preferably tempered steel, whose one end is machined in a way to yield a progressively decreasing diameter so as to reduce the angle between the tool's axis and the luminous beam coming from outside. The opposite end of the stem can be connected to an appropriate motor system, preferably by means a quick release mechanism.

This stem can move about within a rigid sheath whose end corresponding to the tool yields a reduced diameter so as to constitute a rotation stop, while a certain free-play is left between the stem and the sheath beyond this landing, so as to reduce rubbing. A

We hereby certify that this is a
true and correct translation
according to our knowledge.

08/24/57
BETMAR LANGUAGES

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certain portion of the stem must remain free between the terminal portion driven by this motor system and the sheath's mouth so as to allow the flexible stem to absorb certain potential centering differences.

It is this rigid sheath which is curved so as to leave clear the axial region of the auditory canal's opening. Due to its flexibility, the stem can turn at high speed within the sheath. Rubbing can be decreased by prior introduction of a small quantity of lubricant.

The invention will be better understood by referring to the following description of a curved auricular trepan which constitutes a way of making the invention in question and the attached drawing on which:

Figure 1 represents an elevation cutaway view of the trepan according to the invention:

Figure 2 gives a cutaway view of the head of said trepan.

According to the invention, the tool is essentially composed of a cylindrical steel stem 1, constituted for example by a piano wire, having a diameter on the order of 8/10 mm. one of whose ends 1a is machined down in several stages 2, 2a and prolonged by a honed head 3.

The end of the stem 1b is made with a cylindrical sleeve 4 equipped with a circular stop 5, and shortened in the end piece 6 which can be fit together with a rotating coupler 7, driven by a motor which is not shown.

The stem 1 is protected by a rigid cylindrical metallic sheath 8 whose one extremity 9 is honed and presents within itself a stop 9a in which the end 1a of the tool can twist about. Beyond this stop, the interior conduit of the sheath expands so as to allow a certain free play between the stem 1 and said sheath 8, and opens finally in a flattened cone gradient 10, within a larger cavity 11 in which the handle of the tool 4 is lodged.

The sheath 8 is curved in the central portion 8a and can be attached by its free end 8b to a cuff 12 attached to the motor system. One can thereby remove the stem 1 from the end 8b of the sheath 8 by acting on the handle 4, and replace it with identical stems with differently honed heads 3.

When the handle 4 of the trepan is adapted to the rotating cuff 7, the latter causes the rotation of the stem 1 whose end 1a rotates within the stop 9a of the sheath 8 whereas the honed head 3 turn outside of this sheath.

It is understood that the invention is not limited to the precise details of the preceding description given purely by way of example. Particularly, the tool's end portion or head 3 can have any kind of shape adapted to the use for which the instrument is intended; for example in place of cutting heads for drills and reamers, etc., as foreseen above, one may eventually have non-cutting or differently made heads for instruments acting by percussion or shaking.



SUMMARY

The invention has as its purpose a surgical instrument intended notably for surgical operations carried out in the inner ear through the long and narrow conduit of the auditory canal, specifically an auricular trepan, characterized by the following points considered separately or in combination:

1° This trepan is composed of a solid and flexible stem machined back to a point along successive stops, and prolonged by an appropriately machined head adapted to the use for which the instrument is intended;

2° The flexible stem is attached to a handle which can be driven by motor system;

3° The flexible stem can turn within a preferably rigid sheath whose one extremity is fit out with a stop, within which the flexible stem can rotate, whereas the other extremity is enlarged and open to the outside, said sheath being eventually curved back in the area of its median portion.

Limited liability corporation named:

ÉTABISSEMENTS BEAUDOUIN

By proxy:

G. Beau de Loménie, André Armengaud & G. Houssard

8 -41278 Fascicule price 100 Francs

Regarding the sale of fascicules, contact l'Imprimerie nationale, 27, rue de la Convention, Paris (15°).

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